

Certificate

Full Quality Assurance System Approval Annex II excluding (4) of the Directive on Medical Devices



ECM, Bismarckstr. 106, 52066 Aachen, notified to EC under 0481 hereby declares that an examination of the undermentioned quality assurance system has been carried out following the requirements of annex II excluding (4) of the Directive 93/42/EEC.

This certificate is issued on behalf of:

VSY Biotechnology BV

Strawinskylaan 1143, 1077 XX Amsterdam, The Netherlands

ECM certifies that the full quality assurance system under which the products listed in annex I to this certificate are manufactured conforms with the requirements of annex II excluding (4) of the Directive 93/42/EEC on medical devices.

The approved quality assurance system is subject to periodic surveillance as defined by annex II excluding (4), section 5.

This Certificate is only valid for the products mentioned above. Special terms of validity are described in annex I to this certificate.

Any substantial changes of the quality assurance system or the listed products which might affect conformity to annex II of the Directive 93/42/EEC have to be notified to ECM and are subject to a separate assessment.

Audit Report Number

565-18-94

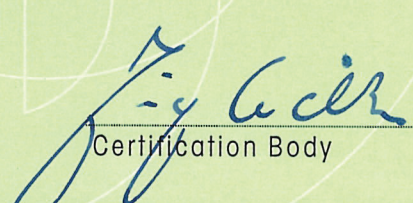
Registered under

Z/18/04341E

Valid until

November 18th, 2023

Valid as of: November 19th, 2018


Certification Body



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-240.10.12

Annex I of Certificate Z/18/04341E

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This certificate is valid for the hereafter following devices:

Name of product category	Name of individual type
Ophthalmic and optical products:	Lenses, Intraocular, Posterior Chamber - Acriva - Ocuva
Ophthalmic and optical products:	Inserters, Intraocular Lens: - AcriJET
Ophthalmic and optical products	Ophthalmic viscosurgical devices - Protectalon 1.0%, 1.2%, 1.4%, 1.6%, 1,8%, 2.0%
non active implantable products	Intra-articular Viscosupplement Medical Devices Reviscon 1.0 % Reviscon Plus 1.6% Romova Plus 1.6 %

Special terms of validity:

None.